



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,367	11/25/2003	Samuel M. Shaolian	ENDOLOG.023CP1	4603

20995 7590 03/05/2009
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

SEVERSON, RYAN J

ART UNIT	PAPER NUMBER
----------	--------------

3731

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

03/05/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/722,367	Applicant(s) SHAOLIAN ET AL.	
	Examiner Ryan J. Severson	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. **Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quiachon et al. (5,769,885) in view of Anderson et al. (5,647,857).** Quiachon et al. disclose a deployment system for a bifurcated graft where the main vessel portion is oriented distal relative to the branch vessel portions (see figures 7 and 30). The deployment system further includes an outer sheath (160) and an inner core (54) with a distal tip (80). Branch vessel restraints (132 and 202) hold the branch vessel portions and a main vessel restraint (93) holds the main vessel. An RO marker (166) is disposed on the outer sheath. However, Quiachon reference does not disclose the main and branch vessel graft restraints are peelable. Attention is drawn to Anderson et al. who teach the use of a peelable sheath (restraint) over a graft with a release element (30, see figures 1 and 2) to allow the sheath to be peeled away from the graft instead of slid or displaced axially to prevent the retraction of the sheath from displacing or distorting the graft during deployment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the restraints of the device of Quiachon et al. peelable, as taught by Anderson et al., to prevent the retraction of the sheath from displacing or distorting the graft during deployment.

Response to Arguments

3. Applicant's arguments filed 02 December 2008 have been fully considered but they are not persuasive.

4. Applicant first argues Quiachon and Anderson both fail to disclose a self-expanding prosthesis. However, applicant is simply incorrect in this regard. Examiner refers applicant to column 17, lines 12-23 of Quiachon, which makes clear the prosthesis of Quiachon is self-expanding. Therefore, this argument is not persuasive.

5. Applicant argues no specific rationales or benefits are set forth as a motivation for the proposed combination. Initially, Examiner notes that making a modification in an obviousness rejection does not require a specific benefit to be achieved. Obviousness rejections are based on what one of ordinary skill would have recognized as being within the level of one of ordinary skill in the art. Further, the combination set forth above is merely a combination of known prior art elements, which is within the level of one of ordinary skill in the art. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

6. Applicant argues Quiachon only has a single restraint, and not three separate restraints. However, Examiner reiterates that which was cited above and in the previous action, that two branch restraints (132 and 202) and a main portion restraint (93) are disclosed in Quiachon. These restraints surround the self-expanding portions of the prosthesis (see figures 1, 7, 8, 24, 27 and 30). Figure 30 shows most clearly all three restraints disposed about the prosthesis. Therefore, this argument is also not persuasive.

Art Unit: 3731

7. Examiner notes that the stent and graft structure of Anderson was not relied upon for any part of the rejection, and therefore arguments directed to this distinction are by nature moot and can not be persuasive.

8. In response to applicant's argument that one of ordinary skill in the art could not combine Quiachon and Anderson, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Again, Quiachon discloses the use of three separate restraints, and making restraints peelable is within the level of one of ordinary skill in the art and is explicitly taught by Anderson. Therefore, this argument is also not persuasive.

9. Applicant argues distal capsule is not a tip because it does not extend beyond the distal extremity of the catheter shaft. However, Examiner can find no claim limitations requiring this "tip" to extend distally beyond all other structures of the deployment system. The claims only require the tip to be situated "adjacent" the distal end of the catheter body. Structure 90 is clearly the distal tip of the inner core (54, see figure 4) and therefore this argument is not persuasive.

10. To summarize, none of the arguments set forth in the response have been considered persuasive and therefore the rejection as a whole has been maintained.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan J. Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:30-5:00.

14. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. S./
Examiner, Art Unit 3731
26 February 2009

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731